

### Remarks

Applicants respectfully request reconsideration of the above-referenced patent application.

#### **I. Claim amendments**

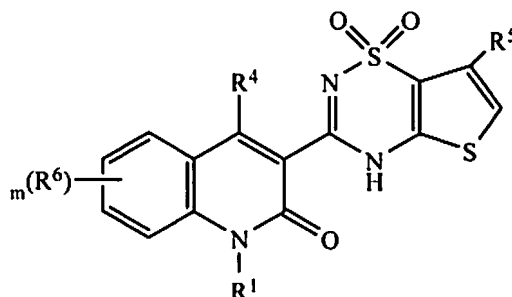
This response does not cancel, add, or amend claims. Thus, claims 25-28, 30-35, 52-57, 62-71, 74, and 90-97 are pending. All pending claims are shown above.

#### **II. Response to the 35 U.S.C. §102(e) rejection**

The Office action rejects claims 25-27, 30-35, and 93-95 under 35 U.S.C. §102(e) for lacking novelty in view of the abstract and pages 1-8 and 33 of Darcy et al. (WO03059356A2). Applicants respectfully request withdrawal of the rejection. In support of their request, Applicants (a) respectfully point to page 3 of the Office action, which correctly states that “Darcy et al. do not exemplify the instant compounds and their [cis] use in a method for treating hepatitis C” thus negating the novelty rejection on page 2 of the Office action, and (b) discuss the novelty of the rejected claims over Darcy et al.

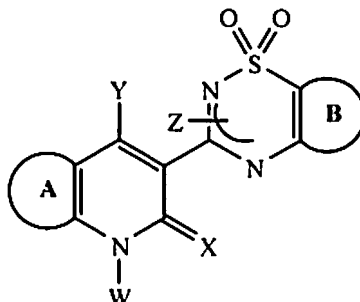
##### **A. Claim 25**

Claim 25 recites compounds (including salts, stereoisomers, and tautomers) of formula Vb:



In formula Vb, R<sup>5</sup> is R<sub>a</sub>SO<sub>2</sub>N(R<sub>f</sub>)-, R<sub>a</sub>SO<sub>2</sub>N(R<sub>f</sub>)alkyl-, R<sub>a</sub>R<sub>b</sub>NSO<sub>2</sub>N(R<sub>f</sub>)-, or R<sub>a</sub>R<sub>b</sub>NSO<sub>2</sub>N(R<sub>f</sub>)alkyl-.

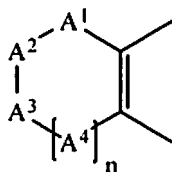
On pages 3-8, Darcy et al. discuss an extremely large genus of compounds of formula I:



In formula I:

A is an accessible fused ring moiety that is an aromatic 6-membered carbocyclic ring moiety or a saturated, unsaturated or aromatic 5 or 6-membered heterocyclic ring moiety, wherein said heterocyclic ring moiety contains one, two or three heteroatoms selected from oxygen,

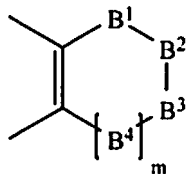
nitrogen and sulfur, represented by Formula II:



where:

$A^1$  is  $CR_{A^1}$ ,  $CHR_{A^1}$ , N,  $NR_{A^1}$ , O or S;  
 $A^2$  is  $CR_{A^2}$ ,  $CHR_{A^2}$ , N,  $NR_{A^2}$ , O or S;  
 $A^3$  is  $CR_{A^3}$ ,  $CHR_{A^3}$ , N,  $NR_{A^3}$ , O or S;  
 $A^4$  is  $CR_{A^4}$ ,  $CHR_{A^4}$ , N,  $NR_{A^4}$ , O or S;  
 n is 0 or 1;

B is an accessible fused ring moiety that is an aromatic 6-membered carbocyclic ring moiety or a saturated, unsaturated or aromatic 5 or 6-membered heterocyclic ring moiety, wherein said heterocyclic ring moiety contains one, two or three heteroatoms selected from oxygen, nitrogen and sulfur, represented by Formula III:



where:

$B^1$  is  $CR_{B^1}$ ,  $CHR_{B^1}$ , N,  $NR_{B^1}$ , O or S;  
 $B^2$  is  $CR_{B^2}$ ,  $CHR_{B^2}$ , N,  $NR_{B^2}$ , O or S;  
 $B^3$  is  $CR_{B^3}$ ,  $CHR_{B^3}$ , N,  $NR_{B^3}$ , O or S;  
 $B^4$  is  $CR_{B^4}$ ,  $CHR_{B^4}$ , N,  $NR_{B^4}$ , O or S;  
 m is 0 or 1;

$R_B^1$  is hydrogen, halogen,  $C_1$ - $C_4$  alkyl,  $-OR_{10}$ , or oxo;

$R_B^2$  is hydrogen,  $C_1$ - $C_8$  alkyl,  $C_2$ - $C_8$  alkenyl,  $C_2$ - $C_8$  alkynyl,  $C_3$ - $C_6$  cycloalkyl, heterocycloalkyl, aryl, heteroaryl, nitro, cyano, halogen,  $-C(O)OR_{10}$ ,  $-C(O)R_{10}$ ,  $-C(O)NR_{10}R_{11}$ ,  $-OR_{10}$ ,  $-SR_{10}$ ,  $-S(O)R_{13}$ ,  $-S(O)_2R_{13}$ ,  $-NR_{10}R_{11}$ , protected  $-OH$ ,  $-N(R_{11})C(O)R_{10}$ ,  $-OC(O)NR_{10}R_{11}$ ,  $-P(O)(OR_{10})_2$ ,  $-SO_2NR_{10}R_{11}$ ,  $-SO_3H$ , or  $-N(R_{11})SO_2R_{13}$ ; and

$R_B^3$  is hydrogen, halogen, cyano,  $C_1$ - $C_6$  alkyl,  $-OH$ , or  $OC_1$ - $C_4$  alkyl.

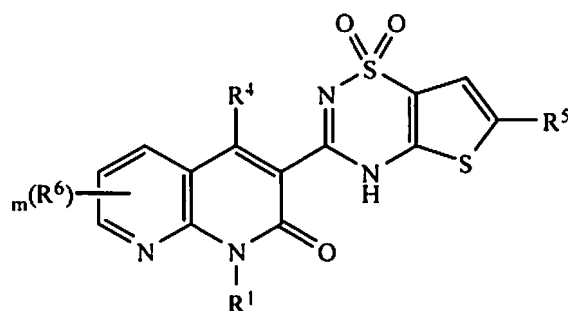
The above genus is not only extremely broad, but its  $R_B^1$  and  $R_B^3$  definitions do not fit the  $R^5$  definition of claim 25 (and, contrary to the Office action's assertion, the  $R_B^2$  definition is not relevant to claim 25 due to the position of  $R_B^2$  on the thienyl ring). The preferred embodiments of the above broad genus that are discussed on pages 11-25 of Darcy et al. also have  $R_B^1$  and  $R_B^3$  definitions that do not fit the  $R^5$  definition of claim 25. Finally, from the forty seven species discussed by Darcy et al., there are only three in which A is phenyl and B is thienyl (see Examples 10, 11, and 13), but none of these three species have the equivalent of  $R^5$  of claim 25. Thus, claim 25 is novel over Darcy et al.

**B. Claims 26 and 27**

Claims 26 and 27 depend from claim 25 and are, therefore, novel over Darcy et al. at least for the reasons discussed above with respect to claim 25.

**C. Claim 30**

Claim 30 recites compounds (including salts, stereoisomers, and tautomers) of formula VIa:



In formula VIa,  $R^5$  is  $R_aSO_2N(R_f)-$ ,  $R_aSO_2N(R_f)alkyl-$ ,  $R_aR_bNSO_2N(R_f)-$ , or  $R_aR_bNSO_2N(R_f)alkyl-$ .

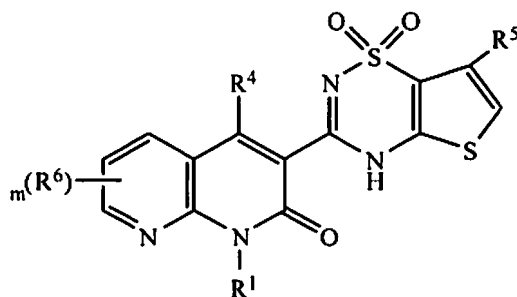
As shown above in the claim 25 discussion, the genus on pages 3-8 of Darcy et al. is so broad that it cannot anticipate claim 30 because one skilled in the art would not be able to envisage from that broad genus the much narrower genus of claim 30. The preferred embodiments discussed on pages 11-25 of Darcy et al. are again either too broad to anticipate claim 30 or limit  $R_B^2$  to exclude  $-N(R^{11})SO_2R^{13}$  -- the only  $R_B^2$  substituent that could arguably correspond to  $R^5$  from claim 30. In addition, none of the forty seven species from Darby et al. have A as in claim 30. Thus, claim 30 is novel over Darcy et al.

**D. Claims 31 and 32**

Claims 31 and 32 depend from claim 30 and are, therefore, novel over Darcy et al. at least for the reasons discussed above with respect to claim 30.

**E. Claim 33**

Claim 33 recites compounds (including salts, stereoisomers, and tautomers) of formula VIb:



In formula VIb,  $R^5$  is  $R_aSO_2N(R_f)-$ ,  $R_aSO_2N(R_f)alkyl-$ ,  $R_aR_bNSO_2N(R_f)-$ , or  $R_aR_bNSO_2N(R_f)alkyl-$ .

As shown above in the claim 25 discussion, the genus on pages 3-8 of Darcy et al. has  $R_B^1$  and  $R_B^3$  definitions do not fit the  $R^5$  definition of claim 33 (and, contrary to the Office action's assertion, the  $R_B^2$  definition is not relevant to claim 33 due to the position of  $R_B^2$  on the thienyl ring). The preferred embodiments discussed on pages 11-25 of Darcy et al. also have  $R_B^1$  and  $R_B^3$  definitions that do not fit the  $R^5$  definition of claim 33. Finally, as already discussed above with respect to claim 30, none of the forty seven species from Darby et al. have A as in claim 33. Thus, claim 33 is novel over Darcy et al.

**F. Claims 34 and 35**

Claims 34 and 35 depend from claim 33 and are, therefore, novel over Darcy et al. at least for the reasons discussed above with respect to claim 33.

**G. Claim 93**

Claim 93 recites a method for treating an HCV infection by administering one or more compounds (including salts, stereoisomers, and tautomers) of claim 25 and is, therefore, novel over Darcy et al. at least for the reasons discussed above with respect to claim 25.

**H. Claim 94**

Claim 94 recites a method for treating an HCV infection by administering one or more compounds (including salts, stereoisomers, and tautomers) of claim 30 and is, therefore, novel over Darcy et al. at least for the reasons discussed above with respect to claim 30.

**I. Claim 95**

Claim 95 recites a method for treating an HCV infection by administering one or more compounds (including salts, stereoisomers, and tautomers) of claim 33 and is, therefore, novel over Darcy et al. at least for the reasons discussed above with respect to claim 33.

**III. Response to the 35 U.S.C. §103(a) rejection**

The Office action rejects claims 25-27, 30-35, and 93-95 under 35 U.S.C. §102(e) for being obvious in view of Darcy et al. (WO03059356A2). As discussed in detail below, Applicants respectfully submit that the claims are patentable over Darcy et al. and request withdrawal of the rejection.

**A. Claim 25**

As discussed above, claim 25 recites compounds (including salts, stereoisomers, and tautomers) of formula Vb in which  $R^5$  is  $R_aSO_2N(R_f)-$ ,  $R_aSO_2N(R_f)alkyl-$ ,  $R_aR_bNSO_2N(R_f)-$ , or  $R_aR_bNSO_2N(R_f)alkyl$ . As also discussed above, from the forty seven species of Darcy et al., there are only three in which A is phenyl and B is thienyl (see Examples 10, 11, and 13), and none of these three species have the equivalent of  $R^5$  of claim 25. To the contrary, Example 10 has  $R^5$  being bromo and Examples 11 and 13 have  $R^5$

being hydrogen. In addition, as discussed above, Darcy et al. discuss  $R_B^1$  and  $R_B^3$  definitions that do not fit the  $R^5$  definition of claim 25. In fact, Darcy et al. emphasize  $R_B^1$  and  $R_B^3$  definitions that are totally different from the  $R^5$  definition in claim 25. For  $R_B^1$ , see, for example, page 20, lines 25-27; page 22, line 26; page 24, lines 9-12; and page 25, line 22. For  $R_B^3$ , see, for example, page 21, lines 10-11; page 23, line 9; page 24, line 28; and page 25, line 25. As can be seen from Darcy et al., none of the options for  $R_B^1$  and  $R_B^3$  have the sulfonylamino-containing substituent that the compounds of claim 25 have (see  $R^5$  in claim 25). To sum up, Darcy et al. teach away from the compounds of claim 25. Thus, claim 25 is patentable over Darcy et al.

**B. Claims 26 and 27**

Claims 26 and 27 depend from claim 25 and are, therefore, patentable over Darcy et al. at least for the reasons discussed above with respect to claim 25.

**C. Claim 30**

As discussed above, claim 30 recites compounds (including salts, stereoisomers, and tautomers) of formula VIa in which  $R^5$  is  $R_aSO_2N(R_f)-$ ,  $R_aSO_2N(R_f)alkyl-$ ,  $R_aR_bNSO_2N(R_f)-$ , or  $R_aR_bNSO_2N(R_f)alkyl-$ . As also discussed above, none of the forty seven species from Darby et al. have a core as in claim 30 in view of the A definition of Darcy et al. In addition to that, Darcy et al. also emphasize  $R_B^2$  preferred embodiments that exclude  $-N(R^{11})SO_2R^{13}$  -- the only  $R_B^2$  substituent that could arguably correspond to  $R^5$  from claim 30. See, for example, page 20, line 28 to page 21, line 9; page 22, line 27 to page 23, line 8; page 24, lines 13-27; and page 25, lines 23-24. To sum up, Darcy et al. teach away from the compounds of claim 30. Thus, claim 30 is patentable over Darcy et al.

**D. Claims 31 and 32**

Claims 31 and 32 depend from claim 30 and are, therefore, patentable over Darcy et al. at least for the reasons discussed above with respect to claim 30.

**E. Claim 33**

As discussed above, claim 33 recites compounds (including salts, stereoisomers, and tautomers) of formula VIb in which  $R^5$  is  $R_aSO_2N(R_f)-$ ,  $R_aSO_2N(R_f)alkyl-$ ,  $R_aR_bNSO_2N(R_f)-$ , or  $R_aR_bNSO_2N(R_f)alkyl-$ . As also discussed above with respect to claim 30, none of the forty seven species from Darby et al. have a core as in claim 33 in view of the A definition of Darcy et al. In addition, as also discussed above with respect to claim 25, Darcy et al. discuss  $R_B^1$  and  $R_B^3$  definitions that do not fit the  $R^5$  definition of claim 33, and, in fact, emphasize  $R_B^1$  and  $R_B^3$  definitions that are totally different from the  $R^5$  definition in claim 33 and do not have the sulfonylamino-containing substituent that the compounds of

claim 33 have. To sum up, Darcy et al. teach away from the compounds of claim 33. Thus, claim 33 is patentable over Darcy et al.

**F. Claims 34 and 35**

Claims 34 and 35 depend from claim 33 and are, therefore, patentable over Darcy et al. at least for the reasons discussed above with respect to claim 33.

**G. Claim 93**

Claim 93 recites a method for treating an HCV infection by administering one or more compounds (including salts, stereoisomers, and tautomers) of claim 25 and is, therefore, patentable over Darcy et al. at least for the reasons discussed above with respect to claim 25.

**H. Claim 94**

Claim 94 recites a method for treating an HCV infection by administering one or more compounds (including salts, stereoisomers, and tautomers) of claim 30 and is, therefore, patentable over Darcy et al. at least for the reasons discussed above with respect to claim 30.

**I. Claim 95**

Claim 95 recites a method for treating an HCV infection by administering one or more compounds (including salts, stereoisomers, and tautomers) of claim 33 and is, therefore, patentable over Darcy et al. at least for the reasons discussed above with respect to claim 33.

**IV. Response to the provisional obviousness-type double patenting rejection**

The Office action provisionally rejects claims 25-28, 30-35, 52-57, 62-71, 74, and 90-97 as unpatentable over claims 1-3, 6, 7, 15-33, 38-41, 58, 59, and 62 of co-pending U.S. Patent Application No. 12/098,024 under the judicially created obviousness-type double patenting doctrine. Claims 19 and 20 from the '024 application have been allowed and are enclosed as Exhibit A (the rest of the claims from the '024 application have been canceled and filed in a continuation application (i.e., U.S. Patent Application No. 12/613,607)). As can be seen from Exhibit A, claims 19 and 20 in the '024 application recite a process for preparing compounds rather than compounds per se or methods of using compounds. In fact, originally-filed claims 85 and 86 in this application, which recite a process for preparing compounds were restricted out by the October 31, 2003 Office action as encompassing an invention that is patentably distinct from the compounds per se and the methods of using the compounds. In view of that restriction, Applicants respectfully submit that the process claims from the '024 application should not be cited against the pending claims in this application as the basis for an obviousness-type double

patenting rejection (just like the claims from this application were not cited against claims 19 and 20 from the '024 application).

The Office action also provisionally rejects claims 25-28, 30-35, 52-57, 62-71, 74, and 90-97 as unpatentable over claims 1-21 of co-pending U.S. Patent Application No. 11/777,692. Claims 4, 5, and 8-14 from the '692 application have been canceled, and claims 1-3, 6, 7, and 15-21 have issued as claims 1-12, respectively in U.S. Patent 7,538,105B2. Applicants will address this obviousness-type double patenting rejection once there are allowable claims in this application.

\* \* \* \* \*

Applicants authorize the Patent Office to charge \$1,110.00 to Deposit Account No. **01-0025** for the three-month extension. Applicants believe that they do not owe any other fee(s) for this filing. If, however, Applicants do owe any such fee(s), the Patent Office is hereby authorized to charge those fee(s) to Deposit Account No. **01-0025**. In addition, if there is ever any fee deficiency or overpayment under 37 C.F.R. §1.16 or §1.17 in connection with this patent application, the Patent Office is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **01-0025**.

Applicants respectfully submit that the application is in condition for allowance, and request that it be allowed. Applicants request that the Examiner call the undersigned if any questions arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,  
Pratt et al.

/Lydia N. Nenow, Reg 52,530/  
Lydia N. Nenow, PTO Reg. No. 52,530  
Abbott Laboratories  
Dept. 0377, Bldg. AP6A-1  
100 Abbott Park Road  
Abbott Park, IL 60064  
(847) 938-0389 (tel)  
(847) 938-2623 (fax)

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/Lydia N. Nenow, Reg. No. 52,530/  
Lydia N. Nenow, PTO Reg. No. 52,530